## **Complete Summary**

#### **TITLE**

Side effect monitoring practices for non-steroidal anti-inflammatory drugs (NSAIDs): percentage of patients treated with daily NSAIDs (selective or nonselective) with risk factors for developing renal insufficiency for whom serum creatinine is assessed at baseline and at least once in the first year following initiation of therapy.

## SOURCE(S)

MacLean CH, Saag KG, Solomon DH, Morton SC, Sampsel S, Klippel JH. Measuring quality in arthritis care: methods for developing the Arthritis Foundation's quality indicator set. Arthritis Rheum2004 Apr 15;51(2):193-202. PubMed

Saag KG, Olivieri JJ, Patino F, Mikuls TR, Allison JJ, MacLean CH. Measuring quality in arthritis care: the Arthritis Foundation's quality indicator set for analgesics. Arthritis Rheum2004 Jun 15;51(3):337-49. [89 references] PubMed

#### **Measure Domain**

#### **PRIMARY MEASURE DOMAIN**

**Process** 

The validity of measures depends on how they are built. By examining the key building blocks of a measure, you can assess its validity for your purpose. For more information, visit the <u>Measure Validity</u> page.

#### **SECONDARY MEASURE DOMAIN**

Does not apply to this measure

#### **Brief Abstract**

#### **DESCRIPTION**

This measure is used to assess the percentage of patients treated with daily non-steroidal anti-inflammatory drugs (NSAIDs) (selective or nonselective) with risk factors for developing renal insufficiency for whom serum creatinine is assessed at baseline and at least once in the first year following initiation of therapy.

## **RATIONALE**

Monitoring non-steroidal anti-inflammatory drug (NSAID) therapy can reduce the incidence and severity of associated adverse events.

NSAIDs are associated with side effects. The American College of Rheumatology and others recommend specific tests at baseline and follow-up at specified time period.

#### PRIMARY CLINICAL COMPONENT

Non-steroidal anti-inflammatory drugs (NSAIDs); risk factors for developing renal insufficiency; side effect monitoring; serum creatinine

#### **DENOMINATOR DESCRIPTION**

Patients treated with daily non-steroidal anti-inflammatory drugs (NSAIDs) (selective or nonselective) with risk factors for developing renal insufficiency\*

\*Note: For the purpose of this measure, renal insufficiency risk factors include age greater than or equal to 75 years, diabetes mellitus, hypertension, angiotensin-converting enzyme inhibitor or diuretic use

#### **NUMERATOR DESCRIPTION**

Patients for whom serum creatinine is assessed at baseline and at least once in the first year following initiation of therapy

## **Evidence Supporting the Measure**

## **EVIDENCE SUPPORTING THE CRITERION OF QUALITY**

- A clinical practice guideline or other peer-reviewed synthesis of the clinical evidence
- A formal consensus procedure involving experts in relevant clinical, methodological, and organizational sciences

## **Evidence Supporting Need for the Measure**

#### **NEED FOR THE MEASURE**

Unspecified

#### **State of Use of the Measure**

#### **STATE OF USE**

Current routine use

#### **CURRENT USE**

## **Application of Measure in its Current Use**

#### **CARE SETTING**

Ambulatory Care
Physician Group Practices/Clinics

#### PROFESSIONALS RESPONSIBLE FOR HEALTH CARE

Advanced Practice Nurses Physician Assistants Physicians

#### LOWEST LEVEL OF HEALTH CARE DELIVERY ADDRESSED

Individual Clinicians

#### **TARGET POPULATION AGE**

Unspecified

#### **TARGET POPULATION GENDER**

Either male or female

#### STRATIFICATION BY VULNERABLE POPULATIONS

Unspecified

## **Characteristics of the Primary Clinical Component**

#### INCIDENCE/PREVALENCE

Unspecified

#### **ASSOCIATION WITH VULNERABLE POPULATIONS**

Unspecified

## **BURDEN OF ILLNESS**

Renal risks of nonselective NSAIDS. At least 8 case-control studies have reported an increased risk of both acute and chronic renal dysfunction with use of nonselective NSAIDs. In contrast, a large prospective cohort over a 14year study period, the Physician's Health Study (n = 11,032) found no associations between self-reported use of acetaminophen, aspirin, or other NSAIDs and elevated serum creatinine (greater than or equal to 1.5 mg/dl) or

- reduced creatinine clearance (less than or equal to 55 ml/minute). The results of this large cohort study are further substantiated by 2 additional cohort studies that did not identify any association between NSAID use and long-term renal adverse events.
- Renal risks of COX-2-selective NSAIDs. Predominately observational study data using surrogate endpoints, and to a lesser extent RCT results, demonstrate increased risk of renal toxicity with nonselective and COX-2selective NSAIDs.

#### **EVIDENCE FOR BURDEN OF ILLNESS**

Saag KG, Olivieri JJ, Patino F, Mikuls TR, Allison JJ, MacLean CH. Measuring quality in arthritis care: the Arthritis Foundation's quality indicator set for analgesics. Arthritis Rheum2004 Jun 15;51(3):337-49. [89 references] PubMed

#### **UTILIZATION**

Unspecified

#### **COSTS**

Unspecified

**Institute of Medicine National Healthcare Quality Report Categories** 

#### **IOM CARE NEED**

Living with Illness

#### **IOM DOMAIN**

Effectiveness Safety

#### **Data Collection for the Measure**

#### **CASE FINDING**

Users of care only

#### **DESCRIPTION OF CASE FINDING**

Patients treated with daily non-steroidal anti-inflammatory drugs (NSAIDs) (selective or nonselective) with risk factors for developing renal insufficiency

#### **DENOMINATOR SAMPLING FRAME**

Patients associated with provider

#### **DENOMINATOR INCLUSIONS/EXCLUSIONS**

#### **Inclusions**

Patients treated with daily non-steroidal anti-inflammatory drugs (NSAIDs) (selective or nonselective) with risk factors for developing renal insufficiency\*

\*Note: For the purpose of this measure, renal insufficiency risk factors include age greater than or equal to 75 years, diabetes mellitus, hypertension, angiotensin-converting enzyme inhibitor or diuretic use.

#### **Exclusions**

Unspecified

#### RELATIONSHIP OF DENOMINATOR TO NUMERATOR

All cases in the denominator are equally eligible to appear in the numerator

## **DENOMINATOR (INDEX) EVENT**

Therapeutic Intervention

#### **DENOMINATOR TIME WINDOW**

Unspecified

#### **NUMERATOR INCLUSIONS/EXCLUSIONS**

#### **Inclusions**

Patients for whom serum creatinine is assessed at baseline and at least once in the first year following initiation of therapy

#### **Exclusions**

Unspecified

# MEASURE RESULTS UNDER CONTROL OF HEALTH CARE PROFESSIONALS, ORGANIZATIONS AND/OR POLICYMAKERS

The measure results are somewhat or substantially under the control of the health care professionals, organizations and/or policymakers to whom the measure applies.

#### **NUMERATOR TIME WINDOW**

Fixed time period

#### **DATA SOURCE**

Administrative data Laboratory data Medical record Pharmacy data

## LEVEL OF DETERMINATION OF QUALITY

Individual Case

#### PRE-EXISTING INSTRUMENT USED

Unspecified

## **Computation of the Measure**

#### **SCORING**

Rate

#### **INTERPRETATION OF SCORE**

Better quality is associated with a higher score

#### ALLOWANCE FOR PATIENT FACTORS

Unspecified

#### STANDARD OF COMPARISON

Internal time comparison

## **Evaluation of Measure Properties**

#### **EXTENT OF MEASURE TESTING**

A multidisciplinary expert panel comprised of nationally recognized experts discussed and rated the validity of each of the proposed measures based on the evidence and their expert opinion using a modification of the RAND/UCLA Appropriateness Method.

#### **EVIDENCE FOR RELIABILITY/VALIDITY TESTING**

MacLean CH, Saag KG, Solomon DH, Morton SC, Sampsel S, Klippel JH. Measuring quality in arthritis care: methods for developing the Arthritis Foundation's quality indicator set. Arthritis Rheum2004 Apr 15;51(2):193-202. PubMed

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## **Identifying Information**

## **ORIGINAL TITLE**

Quality indicator 10. Side effect monitoring practices for NSAIDs: risk of renal insufficiency.

#### **MEASURE COLLECTION**

The Arthritis Foundation's Quality Indicator Project

#### **MEASURE SET NAME**

The Arthritis Foundation's Quality Indicator Set for Analgesics

#### **SUBMITTER**

**Arthritis Foundation** 

#### **DEVELOPER**

Arthritis Foundation RAND Health University of Alabama at Birmingham

#### **ADAPTATION**

Measure was not adapted from another source.

#### **RELEASE DATE**

2004 Jun

#### **MEASURE STATUS**

This is the current release of the measure.

#### SOURCE(S)

MacLean CH, Saag KG, Solomon DH, Morton SC, Sampsel S, Klippel JH. Measuring quality in arthritis care: methods for developing the Arthritis Foundation's quality indicator set. Arthritis Rheum2004 Apr 15;51(2):193-202. PubMed

Saag KG, Olivieri JJ, Patino F, Mikuls TR, Allison JJ, MacLean CH. Measuring quality in arthritis care: the Arthritis Foundation's quality indicator set for analgesics. Arthritis Rheum2004 Jun 15;51(3):337-49. [89 references] PubMed

#### **MEASURE AVAILABILITY**

The individual measure, "Quality Indicator 10. Side Effect Monitoring Practices for NSAIDs: Risk of Renal Insufficiency," is published in "Measuring Quality in Arthritis Care: The Arthritis Foundation's Quality Indicator Set for Analgesics."

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Web site: www.arthritis.org

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Telephone: (310) 393-0411, ext. 7775

Web site: <a href="www.rand.org/health">www.rand.org/health</a> E-mail: <a href="RAND">RAND Health@rand.org</a>

#### **NOMC STATUS**

This NQMC summary was completed by ECRI on August 7, 2007. The information was verified by the measure developer on September 10, 2007.

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